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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/627,580	07/28/00	WOUDENBERG	T 429103

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PATTI SELAN, PATENT ADMINISTRATOR
APPLIED BIOSYSTEMS
850 LINCOLN CENTRE DRIVE
FOSTER CITY CA 94404

EXAMINER	
SHAHNAN-SHAH, K	
ART UNIT	PAPER NUMBER

1645

DATE MAILED:

05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/627,580

Applicant(s)

WOUDENBERG ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/28/2000, 10/13/2000 and 10/23/2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Detailed Action

1. Applicants preliminary amendment, received July 28, 2000, paper # 4 is acknowledged.

Claims 2-40 were canceled.

2. Information disclosure statement, received October 13, 2000, paper # 2 is acknowledged.
3. Request for a corrected filing receipt, received October 23, 2000, paper # 3 is acknowledged.
4. Currently claim 1 is pending and under consideration.

Specification Informalities

5. The disclosure is objected to because of the following informalities: What appear to be typographical errors. Appropriate corrections are required.

Specification page 6, line 28 the word "antiben" is not clear and does not make sense. Please correct.

Specification page 13 line 1 recites the phrase " figs. 3A-3A illustrate the..." which is not clear. Please correct.

Priority

6. Priority was claimed to applications number 09/012,045 and 08/831,983 (specification lines 12-14), which are now issued US patents number 6,126,899 and 6,124,138. Please update case status.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In figure 2 A, item

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(40 a) has not been described in the specification. Correction is required.

Double Patenting

Statutory type (35 U.S.C. 101) double patenting rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 09628076. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Nonstatutory double patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,126,899. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are based on the same device and method. Both claims recite the same device with a very minor difference in the claim language. Claim 1 of the instant application recites “one or more detection chambers” and claim 1 of U.S. Patent No. 6,126,899 recites “two or more detection chambers”. This limitation does not make them patentably distinct because there is no mention of a special embodiment for one detection chamber in the specification. Applicants themselves prefer more than one chamber (see specification page 9, lines 30-31). Also the second chamber can be used as means to run quality control or duplicate sample.

Further more they are based on the same invention, they are identical devices and also U.S. Patent No. 6,126,899 recites the phrase “one or more detection chambers in several places for example (a) abstract line 8, (b) a summary of invention column 2, line 36, (c) description of assay device column 5, line 22 and (d) brief description of the figures column 4 line 42. Both applications uses the same figures in description of the detection chambers (see all figures especially fig 3A-3C)

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Fadler et al. (US Patent No. 4,038,151).

Claim 1 is drawn to a device for detecting or quantitating a plurality of different analytes (multiple analytes) in a liquid sample. Comprising a substrate defining a sample –distribution network of (i) sample inlet, (ii) one or more detection chambers and (iii) channel means providing dead end fluid connection.

Fadler et al. disclose an improved device (card) for detecting or quantitating plurality of different analytes in a liquid sample. (see column 2, lines 27-29). The device comprises a substrate (rigid plastic plate) with a sample distribution network and one or more detection chambers (wells) (see fig 1 column 1). Each of the wells is connected to a predetermined liquid specimen supply port by the means of channels, which provide dead-end fluid connection. The device has means to optically read the viewing wells (see column 2, paragraph 6), can be thermoregulated (see column 4, lines 65-66) and uses vacuum system.

In column 5, lines 34-36 they further teach that: many changes, alterations, modifications and other uses and applications of the subject device will become apparent to those skilled in the art. Also such a device has been commercially available since the early 1980s from Biomerieux-Vitek Microbiology Systems. See (Baileys and Scott's Diagnostic Microbiology 8th edition, pp.

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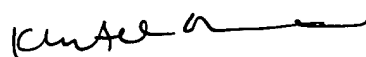
144-147, fig 11.2) and (attached web site advertisement).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 4128101

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER